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JAN 12 1998

Ronald L. Wilson, Director
Health Assessment Policy Staff
Office of Health Affairs (HFY-20)
Food and Drug Administration
5600 Fishers Lane, Room 15-22
Rockville, MD 20857

Dear Mr. Wilson:

The attached application for patent term extension of U.S. Patent No. 5,270,057 was filed on November 25, 1997, under 35 U.S.C. § 156.

The assistance of your Office is requested in confirming that the product identified in the application, FOLLISTIM™ (follitropin beta), has been subject to a regulatory review period within the meaning of 35 U.S.C. § 156(g) before its first commercial marketing or use and that the application for patent term extension was filed within the sixty-day period after the product was approved. Since a determination has not been made whether the patent in question claims a product which has been subject to the Federal Food, Drug and Cosmetic Act, this communication is NOT to be considered as notice which may be made in the future pursuant to 35 U.S.C. § 156(d)(2)(A).

Our review of the application to date indicates that the subject patent MAY NOT be eligible for extension of the patent term under 35 U.S.C. § 156. Another patent owner, Genzyme Corporation (marketing applicant - Serano Laboratories Inc.) has also applied for extension of U.S. Patent No. 5,156,957 based upon the regulatory review period for recombinant human follicle similating hormone (GONAL-F, follitropin alpha/beta), which was approved on the same day as FOLLISTIM™. The regulatory review period in the application for patent term extension for U.S. Patent No. 5,156,957 includes an IND submitted to the FDA on January 24, 1992. It is noted that no IND has been claimed in the application for patent term extension for U.S. Patent No. 5,270,057, but if the testing done by Serano Laboratories Inc. was relied upon by FDA in approving the new drug application (No. 20-582) for FOLLISTIM™, then the regulatory review period cannot be considered to be different than that of GONAL-F.

Inquiries regarding this communication should be directed to the undersigned at (703) 306-3159 (telephone) or (703)308-6916 (facsimile).

Karin Tyson
Senior Legal Advisor
Special Program Law Office
Office of the Deputy Assistant Commissioner
for Patent Policy and Projects

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